

**Notice of Allowability**

Application No.

10/509,139

Examiner

Celia Chang

Applicant(s)

PARTHASARADHI ET AL.

Art Unit

1625

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to examiner's amendment attached.
2. ☒ The allowed claim(s) is/are 6, 7, 13 and 14.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other drawings are approved.

/Celia Chang/  
Primary Examiner, Art Unit 1625

### DETAILED ACTION

1. Response filed by applicants dated May 10, 2010 have been entered and considered carefully.

2. *Examiner's Amendment*

Authorization for this examiner's amendment was given in a telephone interview with Joseph F. Murphy on July 13, 2010.

Claims 1-5. (Cancelled)

6. (Currently Amended): A process for preparation of Form I of (S)-citalopram oxalate ~~as defined in claim 1~~ characterized by an x-ray powder diffraction pattern as in FIG. 1, which comprises:

- a) adding oxalic acid dihydrate to a solution of (S)-citalopram in a suitable solvent;
- b) maintaining the mixture at about 30 minutes for 0°C; and
- c) isolating Form I of (S)-citalopram oxalate; wherein the suitable solvent is selected from the group consisting of ethyl acetate, methyl tert-butyl ether and acetonitrile.

7. (Previously Presented): A process according to claim 6, wherein the suitable solvent is methyl tert-butyl ether.

Claims 8-12. (Cancelled)

13. (Currently Amended): A process for preparation of Form II of (S)-citalopram oxalate ~~as defined in claim 8~~ characterized by an x-ray powder diffraction pattern as in FIG. 2, which comprises:

- a) adding oxalic acid dihydrate to a solution of (S)-citalopram in an alcoholic solvent;
  - b) maintaining the mixture at about 40°C for about 30 minutes, then cooling at about 0°C;
- and

c) isolating Form II of (S)-citalopram oxalate; wherein the alcoholic solvent is selected from the group consisting of methanol and isopropyl alcohol.

14. (Original): A process according to claim 13, wherein the alcoholic solvent is methanol.

15. (Canceled)

16. (Canceled)

3. *Reason for Allowance*

The following is an examiner's statement of reasons for allowance:

By the above examiner's amendment, applicants have canceled the rejected claims and amended the pending claims to be clearly demarcated from the prior art in that the explicit reagent oxalic acid dihydrate which is different from the prior art and the explicit operating conditions in choices of solvents, time and temperature were clearly delineated, thus, with multiple differences which are neither anticipated nor rendered obvious by the art of record. The rejection of claims 6-7 under 35 USC 112 first paragraph for lacking enablement is dropped in view of the newly acquired reference on solvent which indicated that the claimed solvents i.e. ethyl acetate, and acetonitrile have similar Hansen solubility parameter as the exemplified acetone of example 1. Claims 6-7, 13-14 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 113, 2010*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*